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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/721,892

11/26/2003

Mathias Alterman

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05/25/2007

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,892	ALTERMAN ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,11-16,19-27,32-40 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 36-40 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,11-16,19-27 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 11-16, 19-27, 32-40 and 43 are pending in the application.

Response to Amendment

The Amendment filed May 14, 2007 has been entered. The finality of the Office Action dated March 12, 2007 is withdrawn. The following now applies.

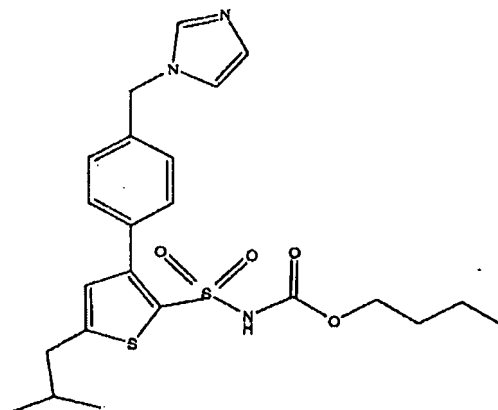
Election/Restrictions

Applicant's election with traverse of IV (claims 1, 5, 9-27 and 32-35), and the species found on page 34, lines 12-13 (reproduced below) in the reply filed on May 17, 2006 was acknowledged in a previous Office Action.

Example 1

**N-Butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthio-
phene-2-sulfonamide**

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The requirement was deemed proper and therefore made FINAL in a previous Office Action.

Claims 36-41 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on May 17, 2006.

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Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: in the Declaration filed May 6, 2004, the filing date of PCT/GB02/02563 is incorrect. The Declaration states that the filing date of PCT/GB02/02563 is January 4, 1990. The oath or declaration is defective.

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Rejections and objections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections and objections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 lacks antecedent basis from currently amended claim 1. See, for example, the eighth compound listed on page 5 of the Amendment filed May 14, 2007.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11-16, 19-27 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. {EP 512,675}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims imidazole compounds. Allen et al. teach imidazole compounds that are structurally similar to the instant claimed compounds and are useful in treating, for example, hypertension (see entire document; especially Formula I on page 3, the variables definitions on pages 3-13; a subclass of the embodiment starting on page 15; the compositions and methods of use on pages 46-49; and the compounds starting on page

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63; particularly a compound such as Compound 51 on page 65).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of Allen et al. and the compounds instantly claimed is that of a hydrogen (as instantly claimed) versus a lower alkyl (as taught by Allen et al., R¹ variable definition on page 3 with variable E defined on page 4 as representing a single bond) on the 2-position of the imidazole ring.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

It is well established that the substitution of a hydrogen atom for a lower alkyl on a known compound is not a patentable modification absent unexpected or unobvious results. In re Lincoln, 53 U.S.P.Q. 40 (C.C.P.A. 1942), In re Druey, 138 USPQ 39 (C.C.P.A. 1963) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A.

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1963). To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e., an angiotension II antagonist).

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught by Allen et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, hypertension. In order to establish patentability in adjacent homologs, there must at least be a persuasive comparative showing establishing distinguishing characteristics allegedly showing that

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claimed compounds are unobvious. Absent a persuasive side by side showing of unexpected, beneficial and superior results of the instant claimed compounds over the compounds taught by Allen et al., the instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

In view of the above rejection of the claims under 35 USC 103 over Allen et al., the elected species of Example 1, found on page 34, lines 12-13 of the instant specification, is not allowable.

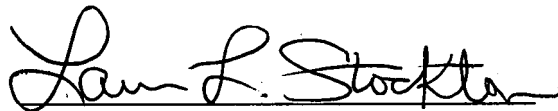
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-069.

Information regarding the status of an application may be obtained from the Patent Application Information

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Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

May 24, 2007